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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,770	12/17/2001	Yoshihito Ikeda	F-7178	2012

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

24.

Office Action Summary**Application No.**

10/018,770

Applicant(s)

IKEDA ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6-8,10-14 and 19 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1, 4, 6-8, 10-14 and 19 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) ☐ Notice of Informal Patent Application (PTO-152)
 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 4, 2004, has been entered.

Claims 1, 4, 6-8, 10-14 and 19 are pending and are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "rapidly reconstituteable" is indefinite because it is not clear how quickly the product recited in

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the claims must be reconstituted, in order to be encompassed by the claims. Because the term "rapidly" is an entirely relative term, a speed of reconstitution considered by one practitioner would to be rapid would not necessarily be considered rapid by another practitioner. Thus, the term "rapidly" does not set out consistent metes and bounds for the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1, 4, 6-8, 10-14 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 9-117279 in view of JP 1-304882.

JP '279 discloses the preparation of the claimed lecithin-derived SOD for therapeutic uses. See English language abstract; see also page 4 of English translation, provided herewith. JP '279 differs from the cited claims in not combining the SOD derivative with a carrier which allows for the storage properties recited in the claims. However, JP '882 clearly discloses that combination of SOD with sucrose results in a stable SOD preparation suitable for storage. See English language abstract; see also "Embodiment 3", at pages 9 and 10 of the English translation provided herewith. Thus, the artisan of ordinary skill seeking to store the SOD derivatives of JP '279, recognizing from JP '882 that addition of sucrose would improve the storage stability of the SOD derivatives, clearly would have been motivated by JP '882 to have combined the SOD derivatives of '279 with sucrose to have rendered them stable for storage. A reasonable expectation of success would have been based on the fact that JP '882 discloses that the very same enzyme was rendered storage

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stable by combination with sucrose. A holding of obviousness is therefore required.

All of applicant's argument submitted to date regarding this ground of rejection has been fully considered, and reconsidered, but is not persuasive of error. Applicant urges that no evidence has been provided establishing that the derivatized and non-derivatized enzymes in the two references have the same therapeutic utility such that one would apply stabilization methods, disclosed as being useful with the non-derivatized enzyme, to the lecithin-derived enzyme. Applicant provides two publications, both listing R. Igarashi as first author, in support of the assertion of different therapeutic utility, and urges that the art-demonstrated significant differences in physical and therapeutic properties between the non-derivatized enzyme and the derivatized enzyme would not have led one of ordinary skill seeking to stabilize lecithin-derived superoxide dismutase (SOD) to have looked to literature discussing stabilization of non-derivatized SOD.

It is respectfully submitted that applicant is confusing the potency of the derivatized enzyme with their therapeutic utility. Clearly, as argued by applicant, the

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Igarashi articles demonstrate that lecithin-derived SOD has a higher potency than non-derivatized SOD. However, at bottom, both compounds catalyze the same chemical reactions. Thus, while one might have to administer more of the non-derivatized SOD as compared to the lecithin-derived SOD, the fact remains that the two enzymes are useful for treating the same disorders, just in different amounts.

Moreover, because both compounds catalyze the same chemical reactions, and the catalytic portions of the two molecules is identical, one looking to stabilize both the lecithin-derived enzyme clearly would have looked to agents known to stabilize the enzymatic activity of the non-derivatized enzyme, such agents including the sucrose stabilizing agent disclosed in JP '882. Thus, even if one were to concede that certain conditions were treatable only using the lecithin-derived enzyme, one seeking to stabilize that enzyme clearly would have looked first to prior art describing techniques of stabilizing that enzyme's catalytic activity. Importantly, and contrary to applicant's argument, there is nothing on the record to suggest that the lecithin moiety would have interfered with the ability of sucrose to stabilize the enzyme's activity.

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Conversely, the fact that sucrose preserves the activity of the non-derivatized enzyme clearly provides motivation for using that agent to stabilize a molecule having the identical catalytic activity and identical structure at the critical catalytic site.

Applicant further urges that the specification demonstrates that, unlike sorbitol, sucrose unexpectedly provides an improvement with respect to the number of degradation products resulting from long term storage (peaks of analogues) of the PC-SOD. It is acknowledged that Table 7 demonstrates that sucrose-stabilized PC-SOD yields fewer peaks of analogues compared to other stabilizers (sorbitol, PEG, mannitol) using reverse-phase chromatography as the analytical tool. However, JP '882 does not use reverse phase chromatography as an analytical tool, so it is not clear that the presence of detectable degradation products by reverse phase chromatography demonstrates anything unexpected. Despite this, note that using another technique, gel filtration chromatography, applicant's specification indicates that no peaks of analogues were detected (specification page 31). This data clearly correlates with the data presented in JP '882 using "gel permeation chromatography," apparently the same

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technique, wherein JP '882 generates similar results to those provided by applicant. See, e.g., JP '882 at pages 7-15, Embodiments 7-13. Thus, on the current record it is not clear that sucrose provides any result which was not expected from viewing the disclosure of the JP '882 patent.

Applicant further urges that, unlike the disclosure of JP '882, the lyophilization of PC-SOD in sorbitol yields a product which has undesirable properties upon reconstitution. However, while the unsuitability of sorbitol is noted, despite its suggestion in JP '882, JP '882 also specifically suggests and exemplifies using the claimed compound, sucrose, to stabilize SOD. Thus, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Lastly, the commercial success and great importance of the claimed product is well appreciated and recognized. However, it is respectfully pointed out that to be sufficient to overcome a holding of *prima facie* obviousness under § 103(a), evidence of commercial success must generally be of a very specific and convincing nature,

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providing a clear linkage between the claimed subject matter and the alleged. See, e.g., MPEP § 716.03. It is respectfully submitted that the presently asserted facts do not rise to the level required. The rejection must therefore be maintained.

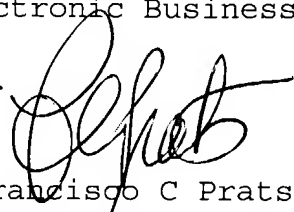
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C Prats
Primary Examiner
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FCP